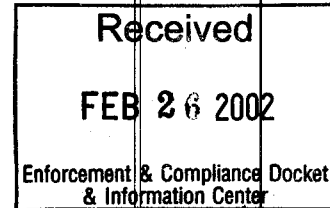


EC-2000-007
IV-D-054

February 25, 2002

U.S. Environmental Protection Agency
Enforcement and Compliance Docket &
Information Center (2201A)
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460



Dear Sir or Madam:

Re: Attention Docket Number EC-2000-007

This constitutes the Tennessee Valley Authority's (TVA) comments on EPA's proposed Cross-Media Electronic Reporting and Recording rule (CROMERRR). Notice of CROMERRR and request for comments was published at 66 Fed. Reg. 46,162-195 (2001). TVA appreciates the opportunity to comment on this important rule.

TVA supports the effort to establish an adequate and uniform protocol for the electronic reporting and recording of information and data for use in EPA regulated programs. Society is moving toward greater reliance on electronic record and telecommunication systems. It is important that regulatory programs establish an appropriate foundation for use of these systems by the regulated community. The potential breadth of CROMERRR alone is immense. EPA's *Federal Register* notice indicates that 17 different EPA regulatory programs could be affected. Care and caution must be used when establishing a protocol of such importance. The extension of the comment period for the proposal indicates that EPA fully appreciates this.

Because of the importance and breadth of the proposal, TVA urges EPA to expressly limit its application to one or two of its regulatory programs for an appropriate period of time. This will allow EPA, the states, and the regulated community time to ensure that the protocol works and is effective. Only after it is successfully piloted and any necessary changes are made should EPA begin extending it to its other regulatory programs. EPA's phased approach to implementing the rule would readily accommodate this.

EPA indicates that subsequent announcements will be made when EPA and its electronic systems are prepared to begin receiving documents in electronic form for specific regulatory programs. Rather than extending CROMERRR to each program as soon as EPA completes the necessary modifications to its electronic systems, our suggestion is that EPA pause after the rule is applied to the first or second program to see how well things are working. This may avoid embedding unsound practices in the electronic systems managed by EPA, the states, and the regulatory community. It would also provide vendors of software and hardware systems a better opportunity to produce commercial products that could meet CROMERRR requirements and thereby reduce potential implementation costs.

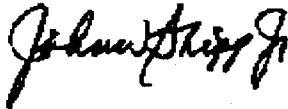
In addition, TVA recommends that EPA issue its schedule for extending CROMERRR to

its various programs. This will allow the states and the regulated community an opportunity to better schedule when adjustments to their electronic systems may have to be made. Very few members of the regulated community are likely subject to all or even most of EPA's various regulatory programs. Entities subject to programs that will be phased into CROMERRR later should be apprised of this so that they can take advantage of improvements to CROMERRR that may result as well as to advances in electronic systems and associated software.

The regulated community has serious concerns about the potential implications of the CROMERRR rule. Although EPA characterizes the rule as voluntary in nature, it is voluntary only if states or the regulated community forbear using electronic systems to report or record information or data that are provided to EPA for regulatory purposes. This is no real choice and could induce behavior that actually slows the transition from paper to electronic documents. The two suggestions TVA makes above should go a long way toward ameliorating fears about CROMERRR.

Additional, more specific comments are enclosed. We join with those that are urging EPA to give this proposal very careful thought before proceeding with it in its current form.

Sincerely,

A handwritten signature in black ink, appearing to read "John W. Shipp, Jr.", written in a cursive style.

John W. Shipp, Jr., P.E.
General Manager
Environmental Policy and Planning

Enclosure

EPA's PROPOSED CROSS-MEDIA ELECTRONIC REPORTING AND RECORDING RULE TVA COMMENTS

This constitutes the Tennessee Valley Authority's (TVA) specific comments on EPA's proposed Cross Media Electronic Reporting and Recording Rule (CROMERRR). Notice of this rule and request for comments was published at 66 Fed. Reg. 46,162-195 (2001).

TVA is a federal instrumentality and government corporation. As part of its regional development mission, TVA operates the Nation's largest integrated electric utility system. TVA's power system serves more than eight million people in parts of seven southeastern states. TVA generates a variety of different reports and data and operates different electronic and telecommunication systems. A number of TVA's activities are subject to various EPA or state-delegated regulatory programs. CROMERRR potentially applies to TVA's use of computer-generated or recorded information and data in its EPA-related compliance activities.

Accordingly, TVA is very concerned that broad application of CROMERRR could significantly increase TVA's compliance reporting and recording costs. In order to convert to or acquire electronic systems for CROMERRR approvable formats and to thereafter operate and maintain these systems, TVA estimates that its initial costs would be \$6 million just to build onto our existing document infrastructure. TVA also estimates that it would take 4 years to complete necessary changes if this had to be done at once for all of TVA's EPA and state-delegated regulatory programs.

TVA has the following additional concerns about the proposal:

1. TVA currently relies on 21 C.F.R. part 11 for guidance on the use of electronic signatures and records. TVA supports EPA's desire to make CROMERRR consistent with these existing FDA rules. However, CROMERRR differs from these rules in several important respects including:
 - The FDA rules set forth what is expected for use of electronic signatures and do not require an electronic signature "agreement." The number of times an individual would be required to sign such an agreement in CROMERRR is excessive. CROMERRR should be changed to require an electronic signature agreement once only.
 - The requirement that systems allowing electronic signatures provide multiple warning screens appears excessive and needlessly increases

system conversion and operating costs. The benefit toward better ensuring authenticity of electronic signatures appears very limited.

- The FDA rules do not require the use of error checking software and requiring this in CROMERRR for data transfer appears excessive.

1. CROMERRR appears to contemplate that states and the regulated community will normally be allowed only one year to meet the rule's requirements as EPA extends the rule from program to program. This is insufficient, especially early on in the rule's implementation. It is not unusual for information system projects of this magnitude in the business community to take three to five years to complete. Implementation periods of this magnitude also have tended to complement software and hardware developments in the computer and telecommunication industries. Providing a schedule for extending CROMERRR to EPA's various programs will help to address this weakness, but TVA recommends that EPA establish a longer period of time at least during initial implementation of the rule.

1. TVA is uncertain where CROMERRR requirements may attach. If electronic systems are used to internally record data and information, but these are converted to paper when submitted to EPA or state regulatory agencies for

assumes that CROMERRR is intended only to apply to information and data recording activities that are intended to result in electronic reporting to EPA or the states for program compliance purposes. EPA should clarify this.

1. EPA should expressly provide that existing electronic data and information recording and reporting systems that are used for compliance purposes remain usable until EPA extends CROMERRR to the regulatory program addressed by these existing systems with appropriate time (three years initially) to convert systems to CROMERRR requirements.